

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0093]

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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution — (21 CFR Part 207)—(OMB Control Number 0910–0045)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the act, FDA issued part 207 (21 CFR part 207). Under § 207.20, manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and biological products, including bulk drug substances and bulk drug substances for prescription compounding, and drug premixes as well as finished dosage forms, whether prescription or over-the-counter, are required to register their establishment. In addition, manufacturers, repackers, and relabelers are required to submit a listing of every drug or biological product in commercial distribution. Owners or operators of establishments that distribute, under their own label or trade name, a drug product manufactured by a registered establishment are not required either to register or list. However, distributors may elect to submit drug listing information in lieu of the registered establishment that manufactures the drug product. Foreign drug establishments must also comply with the establishment registration and product listing requirements if they import or offer for import their products into the United States.

Under §§ 207.21 and 207.22, establishments, both domestic and foreign, must register with FDA by submitting Form FDA–2656 (Registration of Drug

Establishment) within 5 days after beginning the manufacture of drugs or biologicals, or within 5 days after the submission of a drug application or biological license application. In addition, establishments must register annually by returning, within 30 days of receipt from FDA, Form FDA-2656e (Annual Update of Drug Establishment) (Note: This form is no longer mailed to registrants by FDA; updating registration information is estimated in the table below by the information submitted annually on Form FDA-2656). Changes in individual ownership, corporate or partnership structure location, or drug-handling activity must be submitted as amendments to registration under § 207.26 within 5 days of such changes. Distributors that elect to submit drug listing information must submit a Form FDA-2656 to FDA and a copy of the completed form to the registered establishment that manufactured the product to obtain a labeler code. Establishments must, within 5 days of beginning the manufacture of drugs or biologicals, submit to FDA a listing for every drug or biological product in commercial distribution at that time by using Form FDA-2657 (Drug Product Listing). Private label distributors may elect to submit to FDA a listing of every drug product they place in commercial distribution. Registered establishments must submit to FDA drug product listing for those private label distributors who do not elect to submit listing information by using Form FDA-2658 (Registered Establishments' Report of Private Label Distributors).

Under § 207.25, product listing information submitted to FDA by domestic and foreign manufacturers must, depending on the type of product being listed, include any new drug application number or biological establishment license number, copies of current labeling and a sampling of advertisements, a quantitative listing of the active ingredient for each drug or biological product

not subject to an approved application or license, the National Drug Code number, and any drug imprinting information.

In addition to the product listing information required on Form FDA-2657, FDA may also require, under § 207.31, a copy of all advertisements and a quantitative listing of all ingredients for each listed drug or biological product not subject to an approved application or license; the basis for a determination, by the establishment, that a listed drug or biological product is not subject to marketing or licensing approval requirements; and a list of certain drugs or biological products containing a particular ingredient. FDA may also request, but not require, the submission of a qualitative listing of the inactive ingredients for all listed drugs or biological products, and a quantitative listing of the active ingredients for all listed drugs or biological products subject to an approved application or license.

Under § 207.30, establishments must update their product listing information by using Form FDA-2657 and/or Form FDA-2658 every June and December, or at the discretion of the establishment, when any change occurs. These updates must include the following information: (1) A listing of all drug or biological products introduced for commercial distribution that have not been included in any previously submitted list; (2) all drug or biological products formerly listed for which commercial distribution has been discontinued; (3) all drug or biological products for which a notice of discontinuance was submitted and for which commercial distribution has been resumed; and (4) any material change in any information previously submitted. No update is required if no changes have occurred since the previously submitted list.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED REPORTING BURDEN¹

21 CFR Section/Form No.	No. of Respondents	Number of Responses Per Respondent	Total Annual Responses	Hours per Responses	Total Hours
(1) Form FDA-2656 Registration of Drug Establishment 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.26 21 CFR 207.40	18,430	.36	6,700	2.50 hr.	16,750
(2) Form FDA-2656 Annual Update of Drug Establishment 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.26 21 CFR 207.40	8,382	.82	6,859	2.50 hr.	17,147.50
(3) Form FDA-2657 Drug Product Listing 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.30 21 CFR 207.31 21 CFR 207.40	15,530	3	46,713	2.50 hr.	116,782.50
(4) Form FDA-2658 Registered Establishments' Report of Private Label Distributors 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.30 21 CFR 207.31	7,216	2.14	15,415	2.50 hr.	38,537.50
Total Reporting Burden					189,217.50

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of April 8, 2004 (69 FR 18588), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: 7-13-04

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July 13, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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